

**REMARKS**

These remarks are in response to the Office Action mailed June 14, 2006. No claims have been added or amended. No new matter has been introduced by the filing of this paper.

**I. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 9-16 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for predicting the inhibitory action of alcohols on cytochrome P-450 aniline p-hydroxylation and perhaps some other properties of alcohols or simple organic molecules, such as vapor pressure, allegedly does not reasonably provide enablement for predicting or determining the specific activity, chemical or physical property or function of compounds other than alcohols. Specifically, the Examiner alleges that Applicants have not established a correlation between sensor fingerprints and nucleotide or protein sequences. Applicants respectfully traverse this rejection.

It appears to Applicants that the Examiner is viewing the disclosure and evidence of record, not as a whole, but by selectively considering pieces of the disclosure and evidence in a void. Applicants respectfully submit that the data (both in the specification and subsequent references) demonstrate:

- 1) Biological molecules such as DNA can be measured by sensors (e.g., Drummond et al.);
- 2) Other references demonstrate properties including mass can be measured. For example, Ballantine (see below) teaches that mass can be measured by sensors (see, e.g., page 11 of the Office Action);
- 3) Molecular characteristics such as functional groups, hydrogen bonds and chirality can be measured by sensors (specification and subsequent reference);

4) That different sensor types and modalities exist for measuring properties;

5) Post filing reference including issued patents demonstrate analyte properties can predicted using sensors. For example, solubility (see, e.g., U.S. Patent No. 7,117,102), thermal stability and dielectric properties (see, e.g., U.S. Patent No. 6,668,230) and other physical chemical properties (see, e.g., U.S. Patent Nos. 6,625,548; 6,553,318; 6,535,824; 6,535,822; 6,477,749; and 6,438,497).

Applicants respectfully submit that when the claims are viewed in combination with the teachings of the specification and the knowledge of those of skill in the art at the time the invention was made and the evidence provided in the record, the claims are fully supported and enabled for their scope as described more fully below.

Applicants bring to the attention of the Examiner MPEP 2107.03(I):

"A REASONABLE CORRELATION BETWEEN THE EVIDENCE AND THE ASSERTED UTILITY IS SUFFICIENT...An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof....as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

It is important to remember that amino acids/proteins/nucleic acids are chemical compounds. The Examiner has acknowledged that the Applicants have demonstrated alcohol and numerous other chemical compounds can be sensed and analyzed by the invention. Nucleic acids and proteins are chemical compounds comprised of chemical bonds and side groups. Applicants respectfully submit that it has established reasonable correlation between sensor fingerprints and nucleic acids or proteins by providing arguments and reasoning, documentary evidence, and

combinations thereof demonstrating that chemical entities can be predicted, complex polymer characteristics can be predicted such as solubility (see, e.g., U.S. Patent No. 7,117,102), thermal stability can be predicted and complex dielectric properties (see, e.g., U.S. Patent No. 6,668,230).

The Examiner cites a reference about Old Yellow Enzyme to allege the inability to predict an activity of an enzyme. The Examiner's example is irrelevant to the claimed invention as the reference does not demonstrate the use of the claimed invention in identifying the activity of Old Yellow Enzyme, rather the references teaches other computational techniques and thus is unrelated to the systems and methods of the invention. In other words, just because the activity of Old Yellow Enzyme is not known does not defeat the enablement of the claimed invention. Simply put, just because the function of an enzyme is not known using other techniques does not mean the claimed invention is not enabled.

The invention has been demonstrated to recognize a plurality of analyte properties. Accordingly, limiting to a particular property narrows the scope of the claims in view of a broader disclosure supported by the specification and data of record.

The Examiner also appears to be concerned that the scope of the claims is unbounded as to the type of sensor array. However, the Examiner has acknowledged that numerous sensor types and sensing modalities are known in the art (see, e.g., paragraph 0016 of the specification and page 6, last paragraph of the Final Office Action). Applicants (as well as the Examiner) have provided evidence that other sensor types work to measure analyte properties. Applicants submit that to limit the type of sensor would limit the use of the claimed invention in view of a

broader disclosure. The different types of sensor provide different information relative to identifying an analyte. For example, if the sensor array contained only a single type of sensor, only a single interaction of an analyte with the sensor would be probed and reported, thus the profile of data obtained would be limited and thus the ability to "fingerprint" a molecule would be limited.

The Examiner indicates at page 5, ". . . that *others have limited themselves* to more modest goals of predicting a particular property on a select type of analyte, such as monitoring sausage fermentation[], predicting gasoline properties[], or discriminating chirality with simple gas sensors[]." (Emphasis ours). Applicants submit that limiting the invention to a particular analyte, sensor type, or probed property, defeats what the inventors have obtained and are claiming regardless of the desires of "others" to limit their inventions.

The Examiner also questions how one would "select the right sensor for the unknown analyte of interest and the specific activity, chemical or physical property, or function of the analyte to be predicted?" (see page 6 of the Office Action). As mentioned above, selecting one sensor type defeats the claimed invention. It is the interaction of the analyte with a plurality of different sensor types that is used to generate a fingerprint of the analyte. The array of sensor to measure a class of analytes (e.g., DNA, Enzymes, Chemical Compounds) can be developed empirically without undue experimentation so long as the same array is used with the base library and the unknown analyte. For example, mass can be measured on one sensor-type, hybridization on another, changes in absorption/adsorption to a resistive polymer sensor etc. It is not one sensor type or modality that provides the information, it is a compilation ("a profile," a "fingerprint") of a plurality of sensors that

provide the information to probe a database. Applicants have provided evidence that different sensors (mass, hybridization, resistance) all provide signals useful for identifying a particular property, activity, and/or function of an analyte.

The Examiner alleges that the Drummond et al. reference, provided as evidence of enablement, teaches only a specific sensor type and not a plurality of different differentially responsive sensors. Applicants submit that Drummond et al. was provided as evidence of sensors capable of measuring DNA interactions because in prior Office Actions the Examiner questioned whether sensors existed to measure DNA. Drummond et al. was provided to demonstrate sensors exist to measure DNA.

The Examiner further questions whether mass-based transducers can be readily substituted for an electrochemical transducer (see, page 2 of the Office Action). Applicants submit that the Examiner's use of "substituting" one sensor for another appears to indicate that the Examiner does not understand the invention. The array of the invention is not comprised of homogenous/identical sensors. Accordingly, substituting one sensor for another is irrelevant. For example, one would not probe an analyte with a mass-based transducer then *substitute* an electrochemical transducer in place of the mass transducer to probe the unknown analyte as the substitution would change the fingerprint profile.

The Examiner also alleges that although Applicants' invention is not enabled for the scope, it is allegedly obvious in view of Ballantine. "In order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method." *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 13 USPQ2d 1301 (Fed. Cir. 1989) (emphasis added).

Applicants submit that in order to consider the Obviousness rejection (discussed more fully below) the Examiner is inherently admitting the claimed invention is enabled.

Applicants' specification, the Examiner's admissions, and corroborating evidence of sensor modalities (e.g., transducer-types and analyte-types) support Applicants' invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

## **II. REJECTION UNDER 35 U.S.C. §103**

Claims 11, 16, and 17 stand rejected under 35 U.S.C. §103(a) because while allegedly not enabled as set forth above, the invention *is enabled* and allegedly obvious in view of Ballantine Jr. et al., ("Correlation of Surface Acoustic Wave Device Coating Response With Solubility Properties And Chemical Structure Using Pattern Recognition," Anal. Chem. 88:3058-3066, 1986; "Ballantine"). Applicants respectfully traverse this rejection.

As the Examiner correctly points out, Ballantine does not teach or suggest the following elements:

... not including the analyte of interest, identifying the activity, chemical or physical property, or function of at least one known analyte that most closely correlates with the sensor array signal profile, wherein the correlation of the sensor array signal profiles to the previously obtained signal profiles is predictive of a specific activity, chemical or physical property, or function of the analyte of interest. . .

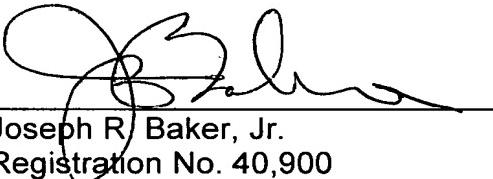
(as recited in Applicants' independent claims). Furthermore, in the *two decades* that have since passed between publication of Ballantine and today, no party has published or described the elements of Applicants' claimed invention. Furthermore, as the Examiner will notice current techniques utilize training samples that include

the analyte of interest as part of the training set, this is drastically different than Applicants' claimed invention.

For at least the foregoing reasons, Applicants submit that the claimed invention is non-obvious over the Ballantine reference. Accordingly, Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

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